

Applicant: Golds et al.
Application Serial No.: 10/716,639
Filing Date: November 19, 2003
Docket No.: 760-57 RCE/CON/RCE
Page 5

REMARKS/ARGUMENTS

Claims 26-34 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent 5,782,904 to White (“White”) in view of U.S. Patent 6,042,605 to Martin et al (“Martin”). In addition, Claims 26-34 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,731,073 to Robinson in view of U.S. Patent 6,042,605 to Martin et al (“Martin”) and U.S. Patent 5,782,904 to White (“White”).

It is respectfully traversed that one of ordinary skill in the art would not be motivated to combine White and Martin or Robinson, Martin and White in an attempt to arrive at the present invention.

The present invention provides a composite stent-graft tubular prosthesis that includes an inner PTFE tubular structure, an outer PTFE tubular structure, and a helically wound stent between the inner and outer tubular structures with selectively chosen peaks of the stent exposed exteriorly of the outer PTFE structure. This provides a composite prosthesis with enhanced flexibility. The outer PTFE tubular structure is constructed to expose segments of the stent exteriorly of the PTFE tubular structure, while maintaining a longitudinally continuous portion. The result is an outer PTFE tubular structure that is extended over the stent, with at least some portion uninterrupted over the entire length of the stent from one end to the other, and other

Applicant: Golds et al.
Application Serial No.: 10/716,639
Filing Date: November 19, 2003
Docket No.: 760-57 RCE/CON/RCE
Page 6

portions providing openings to expose stent segments, thereby selectively enhance flexibility of the device.

White discloses a graft comprising a tubular graft body which is circumferentially reinforced along its length by a plurality of separate, spaced-apart, malleable wires, each of which has a generally closed sinusoidal or zig-zag shape, one of the wires being located adjacent to one end of the graft body such that alternate crests or apices of the wire projects beyond at least part of that end. In contrast to the present invention however, White discloses that:

“the wires are each woven into the fabric of the tube such that alternate crests of each wire are outside the tube with the remainder of that wire inside the tube.”

Col 5, Line24-26.

In the present invention the outer tubular layer, as set forth in independent claim 26 has opening for: “...exposing selective ones of said upper and lower wave-like peaks through said second PTFE tubular structure...” of the stent wires. As can be clearly seen in Figs. 6 and 7 of the White patent and in the disclosure quoted above, White only discloses that alternate crests of each wire are exposed, while the present invention as set forth in independent claim 26 claims that both upper and lower peaks are exposed.

Applicant: Golds et al.
Application Serial No.: 10/716,639
Filing Date: November 19, 2003
Docket No.: 760-57 RCE/CON/RCE
Page 7

Thus, White provides no disclosure, teaching or suggestion of exposing both upper and lower wave-like peaks through said second PTFE tubular structure as in the present invention. Accordingly, independent claim 26 is patentably distinct from White.

Martin is in distinct contrast to the invention as amended. Martin discloses a stent-graft wherein an outer non-overlapping helical coupling member is used to adhere a stent to an inner graft member. The coupling member may be in the form of a ribbon which is helically wrapped to the exterior of the stent or alternatively is woven through the stent. At no point does the ribbon overlap itself to form a continuous tubular structure. Thus, there is no uninterrupted portion along the entire length of the stent from one end to the other in an axial direction. The coupling member is wound about the stent, in an open helical structure, whereby each successive winding is spaced from the other.

The coupling member is precluded from being uninterrupted, i.e., overlapping itself to form a continuous longitudinally portion by the presence of the stent and the helical thread or linking member which holds adjacent stent pieces together. These elements are positioned between the open spaces of the tape as it winds around and through the stent portions. Martin's helical coupling member is configured to be discontinuous and open as a means of performing its coupling function, which is dictated by the stent configuration.

Applicant: Golds et al.
Application Serial No.: 10/716,639
Filing Date: November 19, 2003
Docket No.: 760-57 RCE/CON/RCE
Page 8

Thus, Martin provides no disclosure, teaching or suggestion wherein, as in the present invention the outer tubular layer, as set forth in independent claim 26 has opening for: “...exposing selective ones of said upper and lower wave-like peaks through said second PTFE tubular structure...” of the stent wires. Accordingly, the claim as amended is patentably distinct over Martin and allowable.

Claims 26-34 are also rejected under 35 U.S.C. §103(a) as being obvious over Robinson in view White and Martin. Applicants respectfully traverse.

While Robinson discloses a stent between inner and outer grafts, it is respectfully submitted that Robinson fails to cure the deficiencies of White and Martin. More specifically, there is no teaching or suggestion in Robinson to expose the stent through the outer layer. Nor is there any motivation set forth in Robinson to combine the disclosure of Robinson with the helically wrapped ribbon of Martin or the exposing of alternate peaks through slits as disclosed in White to arrive at the present invention.

Accordingly, it is respectfully submitted that Robinson, White and Marting, individually or in combination, fail to teach or suggest the present invention of claim 26 and all claims dependent therefrom. Withdrawal of the rejection of claims 26-34 are respectfully requested.

Applicant: Golds et al.
Application Serial No.: 10/716,639
Filing Date: November 19, 2003
Docket No.: 760-57 RCE/CON/RCE
Page 9

Moreover, in establishing a *prima facie* case of obviousness, the cited references must be considered for the entirety of their teachings. *Bausch & Lomb, Inc. v. Barnes-Hind, Inc.*, 230 U.S.P.Q. 416, 419 (Fed. Cir. 1986). It is impermissible during examination to pick and choose from a reference only so much that supports the alleged rejection. *Id.* Thus, the specific teachings of White and Martin or Robinson, Martin and White which teach away from the present invention as set forth in the claims must be considered by the examiner.

As there is not motivation to combine White and Martin or Robinson, Martin and White when considering their entire teachings, the only way to arrive at the present invention is through hindsight reconstruction. It is well established, however, that hindsight reconstruction of a reference does not present a *prima facie* case of obviousness and any attempt at hindsight reconstruction using Applicants' disclosure is strictly prohibited. *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1445-46 (Fed. Cir. 1993).

Thus, White and Martin or Robinson, Martin and White, individually or in combination, fail to teach or suggest the subject invention as presently defined by independent claim 26. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) of claim 26, and all claims dependent therefrom, are respectfully requested.

Applicant: Golds et al.
Application Serial No.: 10/716,639
Filing Date: November 19, 2003
Docket No.: 760-57 RCE/CON/RCE
Page 10

Summary

Therefore, Applicants respectfully submit that independent claims 26, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461.

Respectfully submitted,



Stephen Cannavale
Registration No.: 44,585
Attorney for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700